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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/736,267 | 10/24/1996 | KJELL G. E. BACKSTROM | 06275/004001 | 3709 |

7590 12/28/2001

JANIS K FRASER
RISH & RICHARDSON
225 FRANKLIN STREET
BOSTON, MA 021102804

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/736,267

Applicant(s)

Backstrom

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 9, 2001
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-16, 21, 22, 26-32, 50-97, and 101-118 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 21, 22, 26-30, 32, and 50-97 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-10, 12-16, 31, and 101-118 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Pursuant to the directives of paper No. 41 (filed 10/9/01) claims 1, 2, 12, 21, 31, 61, 78, 79, 96, 102, 103, 112, 117 have been amended. Claims 1-10, 12-16, 21, 22, 26-32, 50-97, 101-118 remain pending. Claims 2, 21, 22, 26-30, 32, 50-97 remain withdrawn from consideration.

Applicants' arguments filed 1/16/01 have been considered and found persuasive. To the extent that they have been examined, claims 1, 3-10, 12-16, 31, 101, 102, 103-118 characterized as allowable.

At the present time, prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle* [1935 C.D. 11, 453 O.G. 213]. The remaining issue is that of the restriction (Office action mailed 12/30/99). The restriction originally differentiated between those embodiments which permitted the presence of a non-descript "non-hygroscopic derivative", and those embodiments which excluded such. Applicants elected the second of these ("non-hygroscopic additives" excluded). Accordingly, what is sought is the exclusion of "non-hygroscopic additives" from the claims. Compliance with this directive would include an amendment of claim 1, for example. Applicants have argued that in claim 1, the "non-hygroscopic additives" exclude peptides and surfactants. The examiner disagrees. However, if there is descriptive support for it, claim 1 could be amended to recite that the "non-hygroscopic additives" exclude peptides and surfactants. In introducing such an amendment, however, applicants should point to specific page and

line numbers where support can be found.

An exception to the foregoing is made in the case of claim 102 (and claims properly subgeneric thereto). Although claim 102 contains non-elected subject matter, the restriction will not be enforced in the case of this claim, since the "additives" are limited to specific compounds, or to specific classes of compounds. By contrast, claim 2 encompasses embodiments in which less than 1% of the particles have a diameter of 10 microns, and the remaining 99+% of the particles have a diameter well in excess of 10 microns (this is true even for part (a) of claim 2).

The method claims (e.g., claim 21) do not have to be cancelled. However, claim 21, though recently amended (filed 10/9/01) does not include the limitations of claim 1. For example, claim 21 imposes no limitations on the particle size of the composition, only limitations on that portion of the particles which reach the respiratory tract. Similarly, the claims drawn to a "device" (e.g., claim 78) do not have to be cancelled. However, the limitations of claim 1 would have to be imported into claim 78 for rejoining to take place.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

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Serial No. 08/736,267
Art Unit 1653

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Reference "AR" (Kohler, 1987) was stricken from the IDS because of the absence of a translation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800